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Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 7,060,269 was filed on August 25, 2006, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, LUCENTIS® (ranibizumab), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period set forth in 35 U.S.C. § 156(d)(1). Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Applicant is advised that despite the statement regarding submission of a check in paragraph 14 on page 12 of the application of August 25, 2006, the Office has no record of having received or cashed such a check. Therefore, in accordance with the authorization provided in the same paragraph, the fee of \$1120.00 prescribed in 37 CFR 1.20(j) is being charged to deposit account number 18-1260.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7754 (telephone) or (571) 273-7754 (facsimile).

Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

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